K130183

510(k) Summary

Sponsor: Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

JUL 3 2013

Contact: Maria Rao, QA/RA Director
Ph: 508-226-5660 ext 1206

Trade Name: SFI Bar® Implant Abutments

Common Name: Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II

Product Code: NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):
Predicate Device(s): K083876
K102382

K083876	SFI Bar® System Complete 2-Implant and 4-Implant
K102382	SFI Bar® Implant Adapter Straumann, SFI Bar® Implant Adapter Neos

Description of Device:
Device Description: The SFI Bar® Implant Abutments provide the connection between compatible dental implant systems for the fixation of removable overdentures. The SFI Bar® Implant Abutments consist of an abutment, which is attached to a stress free bar for the fixation of removable overdentures. The implant abutment is screwed into the dental abutment.
The implant abutments fit Nobel Biocare Brånemark System®, Nobel Biocare (Steri-Oss®), Keystone (Lifecore), 3i Implant Inovations®, Sterngold-ImplaMed®, Interpore IMZ™, Osstem, Zimmer (Paragon, Centerpulse), OIC, IMTEC Corporation®, MIS Implants, Minimatic/Stryker, Bud, Straumann, Biolok International , INNOVA, Implant Direct, Zimmer (Calcitek® Centerpulse), BioHorizons®. **See table 1 for platform compatibility.**

There are seven (7) different platforms and each platform is compatible with one or more implant types. The platforms of the abutments are [A], [B], [C], [S], [T], [X], [Z]. Table 1 specifies which dental implants are compatible with these platforms.
The difference between each platform is the internal connection with the specific implant.
The devices are supplied non-sterile, therefore there is no shelf life.

Abutment Insertion
Choose the abutment with the proper cuff height that fits on the existing implant. Abutment platforms should be 1 to 2 mm above the gingival level and approximately parallel to the occlusal plane. However, to allow the subsequent placement of the sections of SFI-Bar® on top of these abutments so that the bars are approximately parallel to the occlusal plane, it may be necessary to choose some abutments with different heights. Abutments are screwed into each implant.

Intended Use of the Device:
The SFI-Bar® Implant Abutments are indicated to be used with dental implants as a prosthetic framework to support and /or retain removable or fixed dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

The SFI-Bar® Implant Abutments are compatible with the following implant systems:

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.O OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ™	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)

Zimmer Dental	3.5 Bio-Vent® X™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head),4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
Straumann	ITI TE™ 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE™ 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder

Summary Technological Characteristics:
The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

The material of the implant abutments conform to ASTM F136, Wrought Titanium 6 Aluminum-4 Vanadium ELI Alloy.

Comparison/Compatibility
Substantial Equivalence:
The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.
To ensure compatibility the following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.
Table 2 summarizes the substantial equivalence comparison to the predicate devices.

Performance Data:

Torque tests, application and functional testing have been conducted to evaluate the performance characteristics of the SFI Bar® Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the SFI Bar® Implant Abutments included in this application are equivalent in performance characteristics to the predicate SFI Bar®. The acceptance criteria were met.

Torque test results indicated that there is sufficiently large safety margin for fracture of the SFI Bar® Implant Abutments specified on this submission to occur when tightening. Test samples torqued above 50 Ncm, well above the implant manufacturer's recommended torque value. There is no risk or possibility of harm to the patient.

Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." Torque tests, application and functional tests have been carried out.

The summary of technological characteristics as well as the torque test, application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

Sterngold Dental, Limited Liability Company
C/O Ms. Maria Rao
Director of Regulatory Affairs
23 Frank Mossberg Drive
ATTLEBORO MA 02703

Re: K130183
Trade/Device Name: SFI Bar® Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 30, 2013
Received: June 3, 2013

Dear Ms. Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lester W. Schultheis Jr
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Acting for
Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130183

Device Name: SFI Bar® Abutments

Indications for Use:

The SFI-Bar® Implant Abutments are indicated to be used with dental implants as a prosthetic framework to support and /or retain removable or fixed dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

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Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Part 21 CFR 801 Subparts D) AND/OR Over-the -Counter Use ____ (21 CFR 807 Subpart D)

Sheena A. Green -S
2013.07.03 08:48:41 -04'00'

for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130183